



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,055	09/09/2003	Kathleen Acrtgeerts	DPP-IV-5001-CI	3118
32793 7590 03/27/2007 TAKEDA SAN DIEGO, INC. 10410 SCIENCE CENTER DRIVE SAN DIEGO, CA 92121			EXAMINER NASHED, NASHAAT T	
			ART UNIT	PAPER NUMBER
			1656	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/27/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/659,055	<b>Applicant(s)</b> AERTGEERTS ET AL.	
	<b>Examiner</b> Nashaat T. Nashed, Ph. D.	<b>Art Unit</b> 1656	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 March 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4, 7, 8, 13, 15-21 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) 17-21 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 4 is/are allowed.
- 6) ☒ Claim(s) 7, 8, 13, 15, 16, and 24-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to..
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-946) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1656

The request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), filed March 1, 2007 in this application is improper because the prosecution of this application was not closed. Thus, the filing is treated as a response to a non-final Office action.

The application has been amended as requested in the communication filed March 1, 2007. Accordingly, claims 5, 6, 11, 12, and 19 have been canceled, claims 1, 7, 8, 10, 15, and 16 have been amended, and new claims 24-26 have been entered. Claims 17, 18, 20, and 21 remain withdrawn from consideration for being directed to non-elected subject matter.

Claims 1, 4, 7, 8, 10, 13, 15, 16, and 24-26 are under consideration.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. 37 CFR 1.821 (d) requires the insertion of a sequence identification number following the mentioning of a protein, which its sequence is disclosed in the sequence listing. Applicants' attempted to perfect their compliance with the sequence rules, but their effort fell short. For example, in example 2, a sequencer identifier has to be inserted after each occurrence of DPPIV. Applicants are **responsible for identifying all instances that require a sequence identifier and insert them through out the specification.**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 8, 10, 13, 15, 16, 24, and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons set forth in the prior Office actions, mailed 2/24/06 and 9/1/2006.

Applicants amended the claims by insertion of the space group and unit cell dimension into claim 1 and 7, and traverse the rejection with regard to claims 15 and 16. They argue that the written description guide lines example 13, which is directed to a genus of proteins comprising SEQ ID NO: 3.

Applicants arguments filed 3/1/07 have been fully considered, but they are found unpersuasive. First, the amendment to claim 7 does not overcome the rejection for lack of written description because the claims are directed to a genus of method, i.e., any method that produces a particular crystal. As indicated in the previous Office action,

Art Unit: 1656

only one crystallization method produced the specific crystal of the application, which is described at page 49 of the specification. With regard to example 13 of the written description guidelines, the fact pattern in the examples and the instant application are different. The facts in example 13 are shown bellow.

**Specification:** The specification describes a protein isolated from liver. A working example shows that the isolated protein was sequenced and determined to consist of SEQ ID NO: 3. The isolated protein was additionally characterized as being 65 kD in molecular weight and having tumor necrosis activity. The specification states that the invention provides variants of SEQ ID NO: 3 having one or more amino acid substitutions, deletions, insertions and/or additions. No further description of the variants is provided. The specification indicates that procedures for making proteins with substitutions, deletions, insertions and/or additions are routine in the art. The specification does not define when a protein ceases to be a variant of SEQ ID NO: 3.

Example 13 does not deal with any crystalline composition, and one of ordinary skill in the art would not read the claims as encompassing a protein crystals. The instant application, however, is directed primarily toward a crystal of DPP IV, and one of ordinary skill in the art would come to the conclusion that claims 15, 16, and new claim 24 read on a crystalline composition. The claims in this application are interpreted in light of the specification being required. Thus, the claims remain rejected. Applicants may overcome this rejection by inserting the phrase "a solution composition" in each of claims 15, 16, and new claim 24. Claims 25 and 26 are included in this rejection because neither the specification nor the prior art teach the crystallization or a crystal of a polypeptide consisting of residues 39-766 of SEQ ID NO: 1. It should be noted that the His-Tagged peptide of SEQ ID NO: 3 for which crystallization is described must have different physical characteristics from that of the untagged polypeptide of residues 39-766 of SEQ ID NO: 1. The His-Tag would be expected to alter the physical characteristics of the polypeptide such as isoelectric point and solubility in different buffers, which are expected to drastically alter the crystallization conditions point.

Claims 7, 8, 10, 13, 15, 16, and 24-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons set forth in the prior Office actions, mailed 2/22/06.

In response to the above rejection, applicants argue that the claims and the specification meet the enablement requirement.

Art Unit: 1656

Applicants arguments filed 3/1/07 have been fully considered, but they are found unpersuasive. Enablement requires a disclosure sufficient to allow a person of skill in the art to practice the full scope of the claimed invention without undue experimentation. The previous Office action sets out a *prima facie* case of non-enablement, explaining by sound scientific reasoning supported by evidence from the prior art why a person of ordinary skill in the art would doubt that the guidance of the specification would enable practice of the full scope of the claimed invention without undue experimentation. Applicants have presented no evidence or, indeed, any arguments to establish the adequacy of the disclosure to enable the scope of the instant claims. Applicants merely assert that the specification meets the enablement requirements. Applicants make no effort to explain why they consider the disclosure of one crystal of SEQ ID NO: 3 prepared by the method described at page 49 to be enabling with respect to any crystallization method to obtain any crystal of SEQ ID NO: 3 or residues 39-766 of SEQ ID NO: 1 (claims 15, 16, 24, and 25), or any method to obtain any specific crystal (claims 7, 8, 10, and 26). Conclusory statements unsupported by evidence or scientific reasoning are insufficient to overcome the *prima facie* case of non-enablement set out in the previous Office action.

Claims 1 and 4 are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTWTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen K. Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1656

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Nashaat T. Nashed, Ph. D.  
Primary Examiner  
Art Unit 1656